



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

93665d

November 7, 2002

Dallas District  
4040 North Central Expressway  
Dallas, Texas 75204-3145

Re: 2003-DAL-WL- 05

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Ronald A. Christensen  
President & General Manager  
Sunnymead Ranch, Inc.  
Rt. 1, Box 49  
Idalou, TX 79329

Dear Mr. Christensen:

An inspection of your feed mill located at Route 1, Idalou, Texas, was conducted by Food and Drug Administration (FDA) Investigator Lisa Yoder on September 9/11, 2002. The inspection found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 — Animal Proteins Prohibited in Ruminant Feed (21 C.F.R. 589.2000). This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). The deviations cause the feed for sheep (a ruminant animal) manufactured at your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Animal feeds and feed ingredients containing any mammalian derived protein (prohibited material), such as bovine meat and bone meal, are considered potentially injurious to ruminant and public health. Therefore, the use of such materials in ruminant feed causes the feed to be adulterated under Section 402(a)(4) of the Act.

Our inspection revealed that your firm manufactures feed for sheep, that may contain residues of prohibited material. Your sheep feed is mixed in the same equipment that is used for mixing chicken feed containing bovine meat and bone meal. Your sheep, which are given this feed, are ultimately auctioned for sale as food for human consumption.

A list of Inspectional Observations (FDA Form 483) was issued to your firm and discussed with you at the conclusion of the inspection. The following violations were observed during the inspection:

Failure to use clean-out procedures or other means adequate to prevent carryover of protein derived from mammalian tissue to animal protein or feeds that may be used for ruminants, 21 C.F.R. 589.2000(e)(1)(iii)(A) and (B). Specifically, raw ingredients, such as soybean meal, limestone, dehydrated alfalfa meal, and meat and bone meal (bovine) pass through shared equipment. Your firm does not conduct any form of clean-out between delivery of meat and bone meal and other feed ingredients like alfalfa meal, limestone, and soybean meal used in both chicken and sheep formulas.

Mr. Ronald A. Christensen, President  
Sunnymead Ranch Inc.  
November 7, 2002

Additionally, there is no clean-out between batches of chicken feed which contain the meat and bone meal and the sheep feed which is not intended to contain the meat and bone meal.

Failure to maintain written clean-out procedures to prevent carryover of protein derived from mammalian tissues to animal protein or feeds that may be used for ruminants, 21 C.F.R. 589.2000(e)(1)(iv). Specifically, your firm does not have any written clean-out procedure to prevent cross-contamination between the sheep feed and the chicken feed nor do they practice/conduct any clean-out procedures to prevent the cross-contamination between the chicken feed and sheep feed.

The above is not intended to be an all-inclusive list of deficiencies by your firm. As a feed manufacturer and ruminant feeder of sheep intended for slaughter as food, you are responsible for ensuring that your operations are in full compliance with the law. We have attached a copy of the BSE regulations to assist you in meeting complete compliance under the law.

We are in receipt of your letter to this office dated September 13, 2002, in which you state your "intent to not manufacture any sheep feed for the immediate future." It is unclear to us from your letter whether you intend to permanently discontinue manufacturing feed for sheep and whether you are now purchasing ruminant feed from some other source. We cannot stress enough the seriousness of these deficiencies, and the importance of your firm being in complete compliance with the BSE regulations in regard to the mixing of ruminant feed, and feeding and marketing of ruminant animals. Your firm must adhere to the regulations to assure a safe ruminant feed and meat supply, or establish complete and separate receiving, mixing, handling, and feeding conveyances and equipment for ensuring such safety.

In your letter, you also indicated your unfamiliarity with the concept of "residuals" of prohibited materials being carried over into ruminant feeds, and you imply that discussions concerning residuals were not held with your firm during FDA's previous inspections. For your information, FDA conducted inspections of your firm on July 27, 1999, and again on December 4, 2001 for coverage of the BSE regulations. During both inspections, investigators questioned your plant manager, John Brown, about the activities of your firm relative to BSE, including specific questions addressing whether your firm was a feeder of ruminant animals. During both inspections, it was also not conveyed to our investigators that your firm raises sheep (for slaughter as food) at this facility or manufactures feed for sheep. Therefore, during each of those inspections no discussion was held regarding "residuals" of prohibited material being carried over to ruminant feeds. We have attached copies of the following FDA guidance documents for your review: FDA Guidance for Industry 68 - Small Entities Compliance Guide - Protein Blenders, Feed Manufacturers, and Distributors; Guide 69 - Feeders of Ruminant Animals With On-Farm Feed Mixing Operations; Guide 70 - Feeders of Ruminant Animals Without On-Farm Mixing Operations; and Guide 76 - Questions and Answers BSE Feed Regulation.

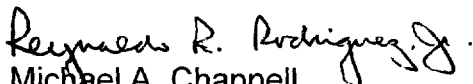
Mr. Ronald A. Christensen, President  
Sunnymead Ranch, Inc.  
November 7, 2002

You should take prompt action to correct these deviations, and establish procedures whereby such violations do not recur. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action could include, but is not limited to seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific actions taken to bring your firm in to compliance with the law. Your response should include an explanation of each step taken, including any plans to be taken to correct the violations that would involve the continued use of the common mixing equipment for both sheep and chicken feeds, and a timeframe for completion of the planned corrections. As part of your written response, you should provide information regarding the current feeding practices for sheep being kept at your facility, and information about the current or planned marketing of such animals for slaughter.

Your written response should be directed to James R. Lahar, Compliance Officer, at the above address. If you have any questions, you may contact Mr. Lahar by telephone at (214) 253-5219.

Sincerely,

  
for Michael A. Chappell  
Dallas District Director

MAC: jrl

Enclosures